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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/370,305	08/09/1999	MALCOLM I. FALCONER	C-314	7927

7590

06/24/2003

BRISTOL MYERS SQUIBB COMPANY
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EXAMINER

BOGART, MICHAEL G

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 06/24/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/370,305

Applicant(s)

FALCONER, MALCOLM I.

Examiner

Michael G. Bogart

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-12, 24, 25, 28-30 and 33-37 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22, 23 and 27 is/are allowed.
- 6) ☒ Claim(s) 13-16, 18, 19, 21, 26 and 31 is/are rejected.
- 7) ☒ Claim(s) 17, 20 and 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 August 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Great Britain on August 13, 1998. It is noted, however, that applicant has not filed a certified copy of the British application as required by 35 U.S.C. 119(b).

Specification

Claim 19 is objected to because of the following informalities:

Claim 19 recites the limitation "the line of attachment" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

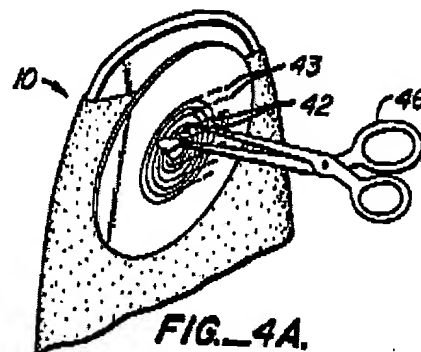
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 31 is rejected under 35 U.S.C. § 102(b) as being anticipated by Eastman (EP 0 231 508 A2).

Eastman teaches an ostomy pouch (10) comprising a pouch envelope (12) and an adhesive wafer (36) for securing the pouch envelope (12) to a person's skin, wherein the wafer cover layer (38) provided on the wafer (36), is provide with guidelines for enabling a person tom

cut the wafer (36) to a desired aperture size, the guidelines including at least one generally circular guideline (42), and at least one generally non-circular guideline (43), and the adhesive wafer (36) being secured to the envelope (12) around a closed line of attachment, that is, the outer perimeter of the pouch (see Fig. 4A, below).



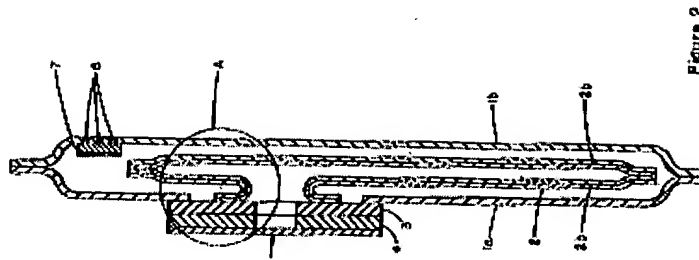
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

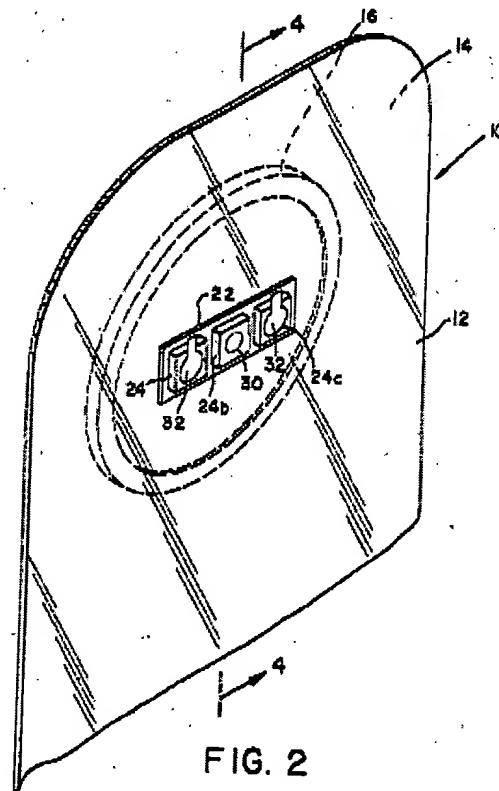
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-16, 18, 19, 21 and 26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Smith *et al.* (US 5,591,144 A) in view of Leise, Jr. (US 4,938,750).

Regarding claim 13, Smith *et al.* teach an ostomy pouch comprising a first wall (2), provided with a comfort layer (1) and a flatus vent (6). Smith *et al.* expressly teach the claimed invention except for a sticker to cover the vent (see Fig. 2, below).



Leise, Jr. teaches an ostomy pouch (10) with adhesive stickers (32) for releasably closing a flatus vent (30)(see Fig. 2, below).



At the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the vent closure means of Leis, Jr. with the drainage bag as taught by Smith *et al.* in order to provide control over the release of flatus from the bag (Leis, Jr. col. 4, line 64-col. 5, lines 8).

Regarding claim 14, Regarding claim 14, Leise Jr. teaches an outlet of the vent (30) defined by at least one segment of plastics material (22) and to which the adhesive sticker means (32) can adhere. Smith *et al.* teaches a outlet of the vent (6) positioned outside the comfort layer (1).

Regarding claim 15, Leis, Jr. teaches a plastics material (22) which has a smooth surface to which sticker means (32) can adhere.

Regarding claim 16, Leis, Jr. teaches a plastics material (22) which is substantially impermeable (col. 4, lines 20-26).

Regarding claim 18, Leis, Jr. teaches a plastics material (22) which is a cover over a filter (28), and is secured to the pouch around the filter (28).

Regarding claim 19, Leis, Jr. teaches a line of attachment which is continuous.

Regarding claim 21, Smith *et al.* teach a comfort layer (1) provided outside the majority of at least an upper portion of the pouch.

Claim 26 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Smith *et al.* and Leis, Jr. as applied to claims 13-16, 18 and 21 above, and further in view of Eastman.

Smith *et al.* and Leis, Jr. teach the claimed invention except for their adhesive wafer being provided with guidelines.

Eastman teaches an ostomy adhesive wafer (36) with a cover (38) provided with circular and non-circular guidelines (42, 43) for enabling a person to cut the wafer (see Fig. 4A).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the indicia of Eastman with the drainage bag as taught by Smith *et al.* and Leis, Jr. in

order to provide a means for adjusting the size of the ostomy aperture (Eastman, page 16, line 27-page 17, line 11).

Allowable Subject Matter

Claims 17, 20 and 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

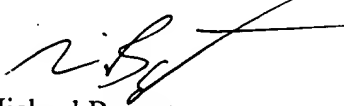
Claims 22, 23 and 27 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (703) 605-1184. The examiner can normally be reached Monday-Friday.

In the event the examiner is not available, the examiner's supervisor, Weilun Lo may be reached at phone number (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 306-4520 for informal communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 306-0858.


Michael Bogart
June 14, 2003


WEILUN LO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700